

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

“A Permanent Solution to the SGR: The Time Is Now”

January 21 & 22, 2015

Submitted Testimony
regarding
Standards of Care and Federal Healthcare Guidelines

The Cooperative of American Physicians, NORCAL Mutual Insurance Company, PIAA, Texas Medical Liability Trust and The Doctors Company would like to thank Chairman Pitts, Ranking Member Green, and the distinguished members of the Subcommittee on Health for providing us this opportunity to submit testimony on the important issue of standards of care as they relate to reform of the Sustainable Growth Rate formula. As leaders within the medical professional liability (MPL) community, we have a great interest in ensuring that all aspects of our health system work for the benefit of both patients and healthcare providers.

Background

MPL (sometimes referred to as medical malpractice or medical negligence) standards of care have traditionally been addressed at the state or local level. Generally speaking, any MPL claim requires a determination of the applicable standard (or duty) of care in the community and whether the medical provider adhered to that standard of care. The standard of care is ordinarily established by an expert witness who relies on a variety of evidence sources such as their own experience, peer-reviewed medical literature, medical specialty society guidelines and practice standards in the state or locality.

Federal Health Care Payment Incentives

During the past decade, the federal government has moved to tie federal payments to healthcare providers to their compliance with requirements intended to improve the cost efficiency or quality of healthcare services. These requirements include the following:

- Tying a portion of Medicare payments to a requirement that physicians electronically prescribe drugs.
- Conditioning Medicare payments to physicians on their compliance with reporting requirements on certain quality measures.
- Denying additional Medicare payments for costs attributable to certain “healthcare acquired conditions” (HACs) that are deemed to have been reasonably preventable.
- Providing incentives to encourage healthcare providers to use certified electronic health records systems (and subsequent penalties for failure to adopt such systems).

These initial efforts to condition federal healthcare payments on the accomplishment of certain objectives were dramatically expanded as part of the Patient Protection and Affordable Care Act (ACA). Under the ACA literally dozens of new payment rules and programs were implemented, including:

- Imposition of a value-based payment modifier for physician services.

- Expansion of the Physician Quality Reporting System that partially conditions payment on quality metrics.
- Creation of Accountable Care Organizations that tie a global payment to cost savings and quality metrics.
- A “bundling” demonstration project that provides a global payment for an episode of care and measures adherence of that care to a variety of measures.
- Expansion of the HAC program to Medicaid and to require payment sanctions under Medicare for hospitals falling into the lowest quartile in terms of the number of HACs.
- Creation of a new Value Based Purchasing modifier for hospital payments.
- Creation of new measures of “avoidable” hospital readmissions and associated payment sanctions for hospitals with excess levels of readmissions.
- A new “quality star” bonus system for Medicare Advantage plans.

Most recently, the *SGR Repeal and Medicare Provider Payment Modernization Act* passed by the House of Representatives last year created additional value-based requirements, including:

- Consolidating the three existing quality programs into a streamlined and improved program that rewards providers who meet performance thresholds, improve care for seniors, and provide certainty for providers.
- Incentivizing care coordination efforts for patients with chronic care needs.
- Introducing physician-developed clinical care guidelines to reduce inappropriate care that can harm patients and results in wasteful spending.
- Requiring the development of additional quality and performance measures.

Please understand that we are extremely supportive of efforts to improve the quality and efficacy of healthcare in the United States. Indeed, MPL insurers are leaders in the effort to improve patient safety and ensure better health outcomes. Our concern, however, is the potential for misuse of regulations and guidelines that are intended to provide better patient care.

The Risk

The drive to tie Medicare and Medicaid payment rules to various incentives intended to promote improvements in cost efficiency and the quality of care has generally been supported on a bipartisan basis, and rightfully so. It must be noted, however, that the rules that have been implemented and will be implemented in the future have not been developed with the intent that they should be applied in medical professional liability cases to determine the applicable standard of care. Indeed, many of the new rules are the subject of sharp disagreement. For example, both the American Hospital Association and the American Medical Association believe that CMS’ list of reasonably

avoidable healthcare acquired conditions is neither accurate nor necessarily demonstrative of the quality of care.

There is a danger in conflating these government payment rules with liability standards and compliance with or deviation from these rules was never intended to serve as the basis for protection from or exposure to litigation. Unfortunately, the beginnings of this trend are starting to appear. A quick search of the internet, for example, reveals dozens of legal websites discussing how the CMS designation of an HAC can ease the burden of demonstrating provider negligence. As insurers, we are also aware of a growing trend at the trial court level to experiment with various theories of liability tied to government payment rules. Consider some of the following potential uses:

- Theories of strict liability or enterprise liability could be applied to hospitals with higher than average HACs or readmissions. Under such theories, actual negligence (deviation from the standard of care) need not be demonstrated.
- Physicians who are in compliance with PQRS reporting requirements with respect to a certain condition, or who receive enhanced payments under the value-based modifier, could argue for plaintiff's to meet a higher standard of proof with respect to proving negligence.
- Plaintiffs could argue that a provider's failure to meet a particular quality metric for their overall population should be evidence of negligence with respect to a particular case where that metric is implicated.
- A Medicare Advantage plan could use its ascertainment of a five star quality rating as a defense to a liability action.

As these examples suggest, the confusion of payment rules with liability rules would be harmful to both the legal process for resolving negligence actions and the government's efforts to promote value based purchasing. Among other outcomes, the development of these payment rules will become embroiled in extensive contention if they are to be allowed to be used as legal evidence.

The Solution

Congress can and should act now to clarify the demarcation of new incentive-oriented payment rules and liability rules. Simple legislative language that articulates that these payment rules should not be construed as liability rules is all that is needed (see attached). Indeed, such language was already included in the SGR repeal legislation which passed the House last year and in the SGR repeal bills put forth by both Republican and Democratic leaders of the Senate Finance Committee.

The scope of this legislation is quite modest. It would simply preserve the status quo with respect to the medical professional liability adjudication process. It would not

change current law, or alter the way courts seek to determine if an act of medical negligence occurred. It would not provide new protections from medical liability lawsuits. It would not, in any way, affect the ability of an expert witness to discuss the applicable standard of care. Instead, it would simply ensure that federal rules and guidelines were not used for legal purposes for which they were never intended, and in the process guarantee the judicial playing field was not inadvertently tipped to favor either defendants or plaintiffs.

The federal government is today at the beginning of a long journey toward greater adoption of payment incentives and systems to promote value in the purchase of healthcare goods and services. Simple and straight forward legislation to clarify at the outset the respective roles of payment rules and liability rules should be adopted to the benefit of all interested parties.

Recommend Standard of Care Language

SECTION 1. SHORT TITLE.

This Act may be cited as the `Standard of Care Protection Act of 2015'.

SEC. 2. RULE OF CONSTRUCTION REGARDING HEALTH CARE PROVIDER STANDARDS OF CARE.

(a) Maintenance of State Standards- The development, recognition, or implementation of any guideline or other standard under any Federal health care provision shall not be construed--

(1) to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim; or

(2) to preempt any standard of care or duty of care, owed by a health care provider to a patient, duly established under State or common law.

(b) Definitions- For purposes of this Act:

(1) FEDERAL HEALTH CARE PROVISION- The term `Federal health care provision' means any provision of the Patient Protection and Affordable Care Act (Public Law 111-148), title I or subtitle B of title II of the Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), or title XVIII or XIX of the Social Security Act.

(2) HEALTH CARE PROVIDER- The term `health care provider' means any individual or entity--

(A) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

(B) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

(3) MEDICAL MALPRACTICE OR MEDICAL PRODUCT LIABILITY ACTION OR CLAIM- The term `medical malpractice or medical product liability action or claim' means a medical malpractice action or claim (as defined in section 431(7) of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11151(7))) and includes a liability action or claim relating to a health care provider's prescription or provision of a drug, device, or biological product (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act).

(4) STATE- The term `State' includes the District of Columbia, Puerto Rico, and any other commonwealth, possession, or territory of the United States.

SEC. 3. PRESERVATION OF STATE LAW.

No provision of the Patient Protection and Affordable Care Act (Public Law 111-148), title I or subtitle B of title II of the Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), or title XVIII or XIX of the Social Security Act shall be construed to preempt any State or common law governing medical professional or medical product liability actions or claims.